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09

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/399,120 09/20/99 MASCARENHAS

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EXAMINER

HM12/0919

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ART UNIT

PAPER NUMBER

1653

DATE MAILED:

09/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/399,120

Applicant(s)
Mascarenhas

Examiner
F. MOEZIE

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1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 28, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above, claim(s) 11-15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

STATUS OF CLAIMS

Claims 1-10 and 16 are pending prosecution in this Office action.

In response to a Restriction Requirement mailed 8/17/01. Applicant elected Group I invention, claims 1-10 and 16, **without traverse**.

The restriction Requirement is made **Final**.

REJECTION - 35 U.S.C. 112, FIRST and SECOND PARAGRAPHS

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue

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experimentation. Citing EX parte Foreman, 230 USPQ 546 (Bd Apls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction and guidance provided,
- 3) The presence or absence of working examples,
- 4) The nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art ‘
- 7) the predictability of the art, and
- 8) the breath of the claims.

Applicant fails to set forth the criteria for the structure and properties of “a null IGF-I”. At page 5, lines 18+, the specification refers to “an amino acid sequence alterations at one or more sites of the molecule” (the specific sites and alterations are too broad and lack enablement). Which sites and what alterations are being claimed (substitution, deletion or modification of the amino acid or etc.) For use in the claimed methods. The only useful sequence that is shown in the specification is Y60L IGF-I. The instant claims read on a myriad of substituted/altered polypeptides and determination of the useful IGF-I for

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the purposes as claimed would necessitate an exhaustive search for determining the useful polypeptide.

In addition, the claims are not enabled for alleviating ALL symptoms of ALL cancers (various cancers). The symptoms for each kind of cancer is different and the claims are not enabled for either detecting or alleviating all symptoms for all cancers.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite regarding the “null IGF-I” as to the number and positions in the substituted and/or altered sequences (if altered - then how are the amino acids altered and at which positions).

The term “symptoms of cancer” render the claims indefinite as to what kind of cancer and which symptoms are intended in the claims.

REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING AN

AMINO ACID SEQUENCE DISCLOSURES IS INCOMPLETE

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The Sequence Listing submitted has been entered into the data base, Aug. 20, 2001.

However, the Sequence Listing compliance is incomplete because:

- 1) The SEQ ID NOS would have to be entered in all Examples and Claim(s), and
- 2) Applicant has failed to comply **fully** with the Requirement since the specification cites other sequences that lack a proper SEQ ID NOS. For example, at pages 10 and 11 (Table I) the designation "N109D,N172D IGFBP-3" lack a Sequence Identifier for IGFBP-3 in the specification.

See, also the underlined portion of the communication from the examiner mailed 6/8/01.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Dr. LOW (SPE) at 308-2923.


F.T. MOEZIE, PH.D.
PRIMARY EXAMINER
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